

REMARKS

Reconsideration and withdrawal of the restriction requirement and election of species are respectfully requested in view of the remarks herewith.

The October 18, 2007 Office Action called for restriction from among the following:

I. Claims 1-11 and 13, drawn to a method for inducing stem cells to differentiated into neuronal cells, and

II. Claim 12, drawn to neuronal cells.

A further election of a single disclosed species was also required. Specifically, if Group I was elected, a single disclosed species of origin of stem cells selected from A) bone marrow, B) placenta, C) muscle, D) brain, E) spinal cord, F) blood or G) skin was required. Also, if Group I or Group II was elected, a single disclosed species of neurons selected from A) dopaminergic, B) serotonergic or C) GABAergic neurons was required.

Applicants elect, with traverse, Group I, bone marrow and dopaminergic neurons.

Applicants reserve the right to file divisional applications to non-elected subject matter.

Reconsideration and withdrawal of the restriction requirement are respectfully requested in view of the remarks herewith.

As a traverse, it is noted that the MPEP lists two criteria for a proper restriction requirement. First, the inventions must be independent or distinct. MPEP § 803. Second, searching the additional inventions must constitute an undue burden on the examiner if restriction is not required. *Id.* The MPEP directs the examiner to search and examine an entire application “[i]f the search and examination of an entire application can be made without serious burden, ...even though it includes claims to distinct or independent inventions.” *Id.*

Groups I and II are both directed to methods of inducing cells to differentiate into neuronal cells comprising a) culturing the cells with basic fibroblast growth factor, culturing the cells of step a) with fibroblast growth factor 8 and Sonic Hedgehog and c) culturing the cells of step b) with brain-derived neurotrophic factor and the neuronal cells derived from the methods of Group I. It is respectfully submitted that any search for the methods of the Group I claims will certainly encompass references for the neuronal cells of the Group II claims. The groups are inextricably linked in that they all involve methods of inducing cells to differentiate into neuronal cells comprising a) culturing the cells with basic fibroblast growth factor, culturing the

cells of step a) with fibroblast growth factor 8 and Sonic Hedgehog and c) culturing the cells of step b) with brain-derived neurotrophic factor and the neuronal cells derived from this method. Therefore, it is respectfully submitted that it would not place an unnecessary burden on the Examiner to search and examine all groups together, as a search for the Group I methods would necessarily include the Group II neuronal cells.

Claims 9-10 are generic claims listing the species of origin of stem cells as a Markush group. Claims 1 and 12 are also generic claims relating to species of neurons. The Examiner is respectfully requested to review M.P.E.P. § 803.02 which states “[i]f the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions.” Furthermore, in view of M.P.E.P. § 803, when the generic claim includes sufficiently few species that a search and examination of all the species at one time would not impose a serious burden on the examiner, then a requirement for election is inappropriate.

In the instant case, there is a disclosure of relationship between the claimed species. Applicants' claims are directed to methods of inducing cells to differentiate into neuronal cells comprising a) culturing the cells with basic fibroblast growth factor, culturing the cells of step a) with fibroblast growth factor 8 and Sonic Hedgehog and c) culturing the cells of step b) with brain-derived neurotrophic factor. Consequently, there is a disclosed relationship between the species as the stem cells are all induced to differentiate into neuronal cells. Additionally, the claims are not broken into separate classifications on the basis of which species is claimed. Consequently, it can be assumed that the classification of all the claims into a single group was made considering each of the species, such that the search of any species would be co-extensive and include the remaining species.

In summary, enforcing the present restriction requirement would result in inefficiencies and unnecessary expenditures by both the Applicants and the PTO, as well as extreme prejudice to Applicants (particularly in view of GATT, whereby a shortened patent term may result in any divisional applications filed). Restriction has not been shown to be proper, especially since it has been shown that the requisite showing of serious burden has not been made. Indeed, the search

and examination of each Group would be likely to be co-extensive and, in any event, would involve such interrelated art that the search and examination of the entire application can be made without undue burden on the Examiner, especially as the claims of all Groups have identical classifications. All of the preceding, therefore, mitigate against restriction.

Consequently, reconsideration and withdrawal of the restriction requirement are respectfully requested.

CONCLUSION

In view of the remarks herein, reconsideration and withdrawal of the restriction requirement are requested.

Early and favorable consideration of the application on the merits, and early Allowance of the application are earnestly solicited.

No fee is believed to be due. The Commissioner is authorized to charge any fee occasioned by this paper, or credit any overpayment in fees, to Deposit Account No. 50-0320.

Respectfully submitted,
ATHERSYS INC.
FROMMER LAWRENCE & HAUG LLP

By: Deborah L. Lu
Anne Brown, Ph.D.
Reg. No. 36,463
Tel. No. (216) 426-3586
Fax No. (216) 432-2461
William F. Lawrence
Reg. No. 28,029
Deborah L. Lu, Ph.D.
Reg. No. 50,940
Tel. No. (212) 588-0800
Fax No. (212) 588-0500